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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,948	05/30/2001	Brian Maiorella	PP00693.104	9747

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[REDACTED] EXAMINER

LIU, SAMUEL W

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1653

DATE MAILED: 09/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/867,948	MAIORELLA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Samuel W Liu	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 May 2001.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 7-38 are cancelled and 1-6 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____    | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Applicants' preliminary amendment filed 30 May 2001 (Paper No. 4) as to cancellation of claims 7-38 prior to patent examination have been entered. Therefore, claims 1-6 are pending and examined in this Office action.

### ***Drawing***

The drawing (Figure 1-3) filed on May 30, 2001 is acceptable subject to correction of the informalities indicated on the attached "Notice of Draftsperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

The following is the information on how to effect drawing changes.

1. New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948. All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in

the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

In addition, Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in abandonment of the application.

***Specification/Objection***

The disclosure is objected to because of the following informalities:

In page 2, line 24, “at 35-37C” should be changed to “35-37 °C”.

In page 3, line 32, “mOsmol/kg” should be spelled out in full at the first instance of use.

See also, page 9, line 36, “ELISA”; page 10, line 20 “Rc LPS”; and page 11, line 21, “rpm”.

In page 6, line 21, H<sub>2</sub>O should be changed to H<sub>2</sub>O”.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 item d) recites “selecting the solute concentration that provides the optimal combination of cell growth and product expression”; the recitation is indefinite as to the claim item c) where at least two concentrations were determined, and it is unclear how the two concentrations are “the solute concentration” for cell optimal product expression (see the recitation “selecting the solute concentrations” wherein the concentrations are plural. The dependent claims are also rejected.

Claim 6 recites the limitation “said monoclonal antibodies”. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6 are rejected under 35 U.S.C. 102 (a) as being anticipated by Rupp, R. G. et al. (GB 2153830).

Rupp et al. disclose a method of improving protein production in animal cell culture under a environment of solute stress (i.e. amino acid mediated hypertonicity) of the culture medium as applied to Claim 1 of the instant application, which comprises: (1) grow the animal cells, hybridoma, to maximum density (see page 3, lines 7-9) and the environmental solute stress promotes hybridoma cell growth via increasing their growth rate (see page 6, lines 56-59 and figure 1) as applied to application Claim 1 item a); (2) increasing the tonicity (i.e. solute stress) by incrementally adding biochemical compounds (see especially page 3, lines 30 –33 and lines 42-43) in order for enhancing the protein production without decreasing cell viability that offers

an advantage for higher protein production (see page 1, lines 40-41), as applied to Claim I item b) of the instant application; and (3) the protein production is carried out under maximum of cell growth in the culture medium being maintained to a desired solute stress condition (i.e. free amino acid-induced hypertonicity) (see especially page 3, lines 7-9, 16-18 and example 1) and the protein-production is monitored by harvesting protein produced by the cells (see page 3, lines 19-20 and , as applied to Claim1 item c) and item d) of the instant application.

Rupp et al. teach the environmental solute stress has beneficial effects on both the protein expression and cell growth rate (see page 6, lines 56-59, page 3, lines 7-9, page 7, lines 7-12 and figures 1 and 3), as applied to Claim 2 of the instant application.

Also, Rupp et al. teach the cell culture is mammalian cell culture (see Claims 1 and 6) expressing monoclonal antibody (see page 1, line 45); the cell is hybridoma cells producing IgG antibody (see Claims 1-13, example 1 and page 3, line 34); and monoclonal antibody is generated from mouse (see page 3, line 33), as applied to Claims 3-6 of the instant application.

#### ***Claim Rejection –Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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Claims 1-6 are rejected under the judicially created doctrine of the obviousness-type double patenting of the claims in US Patent No. 6238891. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1 of US Patent No. 6238891 discloses a method of optimal production of protein in an mammalian cell culture. The method comprises (1) growing the cell in culture medium for optimal growth, as applied to item (a) of the application claim 1; (2) growing the cells under the condition that the solute increases the stress at a concentration above the concentration which is optimal for cell growth (see lines 5-8 of the claim), as applied to item (b) of the application claim 1; and (3) monitoring the protein expression via recovering and purifying protein from the cell culture in order for determining optimal expression, as applied to item (c) of the application claim 1. Claim 12 of US Patent No. 6238891 discloses a method of determining (selecting) a solute concentration in the cell culture in order to produce the highest protein expression, as applied to item (d) of the application claim 1. Additionally, the speciation of US Patent No. 6238891 (see column 5, line 61 to column 6, line6) discloses the identical subject matter and the identical scope of claim 1 of the current application.

Claims 12 of US Patent No. 6238891 discloses that solute concentration that provides the optimal cell growth and protein expression has inhibitory effect on cell growth, as applied to Claim 2 of the instant application.

Claim 1 of US Patent No. 6238891 also disclose a mammalian cell culture being used in the method, as applied to Claim 3 of the instant application.

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Claims 15 and 16 of US Patent No. 6238891 disclose a hybridoma cell culture for monoclonal anybody production wherein the anybody is IgM (see Figure 1a and column 4, lines 37-40), as applied to Claims 4-6 of the instant application.

It is therefore concluded that the claims of the present application are not patentably distinct from the claims of US Patent No. 6238891.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

*Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

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September 23, 2002

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